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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,023	04/02/2004	Salvatore V. Pizzo	5405-304	2746
20792	7590	05/08/2008		
MYERS BIGEL, SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627			EXAMINER	
			LE, EMILY M	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/817,023	Applicant(s) PIZZO ET AL.
	Examiner Emily Le	Art Unit 1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 February 2008.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 14,16-20 and 28 is/are pending in the application.
 4a) Of the above claim(s) 20 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 14,16-19 and 28 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/136/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/21/2008 has been entered.

Status of Claims

2. Claims 1-13, 15 and 21-27 are cancelled. Claim 28 is added. Claims 14, 16-20 and 28 are pending. Claim 20 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/04/2006. Claims 14, 16-19 and 28 are under examination.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The full scope of enablement rejection against claim 17 is withdrawn in view of Applicant's submission, including the Staats declaration. However, a scope of enablement rejection is applicable.

5. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inducing a prophylactic immune response, does not reasonably provide enablement for a method of inducing an immune response to prevent bacterial or viral infections. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claims recite a method of inducing a prophylactic immune response to bacterial or viral infection in a subject.

Lines 13-15, page 14 of the specification discloses: **the present invention can be used prophylactically to prevent...bacterial infections, viral infections, fungal infections, parasitic infections and cancer.** Hence, an aspect of the claimed invention is directed at preventing bacterial or viral infections.

The Office's broadest reasonable interpretation of the term "infection" merely requires that one microorganism gain entry into the cells of a host. In view of this interpretation for the term "infection" and in light of the disclosure, the scope of the claim is also directed at preventing the entry of one microorganism into the cells of a host.

In the instant case, the specification does not contain any working examples showing the prevention of entry of any one microorganism into the cells of a host. Neither the specification nor the art teach a method of preventing the entry of microorganisms into the cells of a host. In view of the lack of teachings in the disclosure and the art demonstrating the prevention of microorganisms into the cells

of a host, the claims are not enabled for the stated scope. In the absence of any teachings or guidance from the specification and art on this particular scope of the claimed invention, the skilled artisan would not be able to practice the full scope of the claimed invention without undue experimentation.

It is noted that in response to the full enablement rejection, Applicant argues that the Office has failed to show evidence that the claimed invention is not enabling for the stated scope. In response to Applicant's argument, the Office has noted that Applicant's specification failed to teach the prevention of entry of microorganisms into a host cell. The absence of any guidance or data relating to the cited scope of the claimed invention establishes a *prima facie* case of lack of enablement for the noted scope.

The issue here is not whether prophylactic immune response requires the prevention of entry of a single microorganism into a cell, as part of its mechanism, as Applicant has alleged. However, the issue here is the Office's interpretation of the term "infection" and how it is used in the context of the claim. In the instant case, the Office interprets the term "infection" to merely require that one microorganism gain entry into the cells of a host. And as presented, the claim reads on a method of inducing a prophylactic immune response, wherein the immune response prevents the entry of bacterial or viral microorganisms into cells of a host. An amendment to the claim that excludes this particular scope would be sufficient to overcome the rejection.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 14, 16-19 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosok et al.¹ in view of Lenney et al.,² as evidenced by Hood et al.³

In response to the rejection, Applicant argues that Rosok et al. does not teach a composition comprising an immunogen and an antimicrobial agent. Rather, Applicant argues that Rosok et al. teaches of composition comprising antibodies and an antimicrobial agent, and its use for the treatment or prophylaxis of *P. aeruginosa* infection with the administration of the composition.

Applicant's arguments have been considered, however, it is not found persuasive. While the entire disclosure of Rosok et al. is directed to antibodies, however, it should be noted that Rosok et al. used the antibodies as an antigen to induce an immune response for the treatment or prophylaxis of *P. aeruginosa* infection with the administration of the composition comprising antibodies and an antimicrobial agent. In the context of cited claim 17 of Rosok et al., Rosok et al.

¹ Rosok et al. U.S. Patent No. 4834976, published May 30, 1989.

² Lenney et al. Antimicrobial action of Compound 48/80 against protozoa, bacteria and fungi. Journal of Pharmaceutical Sciences. May 1977, Vol. 66, No. 5, 702-705

suggested using the antibodies as an antigen. And per Applicant's disclosure, the terms immunogen and antigen are interchangeable. The use of antibodies as antigens is well known in the art at the time the invention was filed. This is evidenced by Hood et al. Hood et al. teaches that antibodies carry new antigenic determinants, called idiotopes, which can behave as antigens to trigger an immune response, wherein the antibodies induced are called anti-idiotype antibodies. In the instant case, Rosok et al. administered the antibodies as antigens to induce an immune response that leads to the treatment or prophylaxis of *P. aeruginosa* infection, wherein the immune response induced would necessarily include the production anti-idiotype antibodies, which indicates a humoral immune response to provide treatment or prophylaxis of *P. aeruginosa* infection. Thus, while Applicant's arguments have been considered, none of the arguments are found persuasive.

In addition to above, Applicant argues that Lenney et al. is silent on immunogens, combining Compound 48/80 with other agents or using Compound 48/80 to raise a therapeutic immune response in the subject. Applicant also argues that combined, Rosok et al. and Lenney et al. fail to disclose every limitation of the claimed invention.

Applicant's arguments have been considered, however, it is not found persuasive. Had Lenney et al. discloses all the elements of the claimed invention, the cited reference would have been cited as anticipating the claimed invention in an anticipatory rejection. Instead, the reference is cited in view of Rosok et al. as

³ Hood et al. Immunology, 2nd Edition. The Benjamin/Cummings Publishing Company, Inc., California,

rendering the claimed invention obvious. Together the reference combined, teach every element of the claimed invention. As discussed in the previous office action, and reiterated below, while Rosok et al. teaches a composition comprising an immunogen and antimicrobial agent with a pharmaceutical carrier, Rosok et al. does not specify the use of Compound 48/80 as an antimicrobial agent. However, at the time the invention was made, Lenney et al. teaches the use of Compound 48/80 as an antimicrobial agent. Hence, at the time the invention was made, it would have been *prima facie* obvious for one of ordinary skill in the art to use compound 48/80 as the antimicrobial agent in the composition of Rosok et al. One of ordinary skill in the art, at the time the invention was made would have been motivated to do so to inhibit microbial growth. One of ordinary skill in the art, at the time the invention was made would have had a reasonable expectation of success for doing so because the Compound 48/80 is an antimicrobial agent. Thus, contrary to Applicant's arguments, Rosok et al. and Lenney et al. combined, teach every element of the claimed invention, thereby rendering the claimed invention obvious. Hence, while Applicant's arguments have been considered, they are not found persuasive.

The claims are directed at the simultaneous administration of an immunogen and compound 48/80 with a pharmaceutical carrier to a subject to induce an immune response. Claim 16, which depends on claim 14, requires that the administration be parenteral. Claim 17, which depends on claim 14, requires the immune response to be a prophylactic immune response to bacterial or viral infection. Claim 18, which

depends on claim 14, requires the immune response to be therapeutic. Claim 19, which depends on claim 14, requires the immune response to comprise a humoral immune response. Newly added claim 28, which depends on claim 14, requires that the administration method be mucosal.

Rosok et al. teaches a composition comprising an immunogen and antimicrobial agent with a pharmaceutical carrier. [Claim 17, columns 28-29, in particular.] Rosok et al. also teaches the administration of the composition to induce a prophylactic and therapeutic immune response against *P. aeruginosa* infection. [Claim 22, column 30, in particular.]

Rosok et al. does not specify the use of Compound 48/80 as an antimicrobial agent.

However, at the time the invention was made, Lenney et al. teaches the use of Compound 48/80 as an antimicrobial agent.

Hence, at the time the invention was made, it would have been *prima facie* obvious for one of ordinary skill in the art to use compound 48/80 as the antimicrobial agent in the composition of Rosok et al. One of ordinary skill in the art, at the time the invention was made would have been motivated to do so inhibit microbial growth. One of ordinary skill in the art, at the time the invention was made would have had a reasonable expectation of success for doing so because the Compound 48/80 is an antimicrobial agent.

Additionally, Rosok et al. teaches that the composition may be administered parenterally. [Lines 57-65, column 8, in particular.] Thus, it would have been *prima*

facie obvious for one of ordinary skill in the art, at the time the invention was made, to administer the composition parenterally. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so facilitate the administration of the composition. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because parental administration is routinely practiced in the art.

While neither Rosok et al. nor Lenney et al. teach mucosal administration methods, however, it would have been prima facie obvious for one of ordinary skill in the art, at the time the invention was made, to use alternative methods of administration, including mucosal or intranasal administration methods. One of ordinary skill in the art, at the time the invention was made, would have been motivated to do so to facilitate the delivery of the pharmaceutical composition rendered obvious by Rosok et al. and Lenney et al. One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because the use of alternative administration methods are routinely practiced in the art.

Conclusion

8. No claims are allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571)272-0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Le/
Patent Examiner, Art Unit 1648

/E. L./